

ESTABLISHING NATIONAL ACCESS AND BENEFIT SHARING REGIMES TO PROTECT BIODIVERSITY: A DEVELOPING COUNTRY PERSPECTIVE

By

Gurdial Singh Nijar
Professor, Law Faculty,
University of Malaya
Kuala Lumpur

I. A NATIONAL LAW ON ABS

Access and benefit sharing (ABS) - definition

'Access' refers to obtaining a country's biological and genetic resources and associated knowledge. The resource taken is expected to yield benefits through its utilization especially by commercialisation. 'Benefit-sharing' refers to the sharing of any benefits derived with the resource provider as a quid pro quo for the access. The benefits could be monetary (royalties, fees) or non-monetary (technology transfer, knowledge, capacity building, research results, patents).

CBD: sovereignty of natural resources

The Convention on Biological Diversity (CBD) provides a new paradigm for countries over their biological and genetic resources. For the first time, an international treaty recognizes the sovereignty of countries over their natural resources; and gives them the right to regulate access to these resources and impose conditions for any such access. The treaty corrects a terrible historical inequity based on the notion that biodiversity, wherever situated, was the 'heritage of mankind'. Biodiversity was historically accessed for free from developing countries. Then products often synthesized from this biodiversity and based on traditional knowledge of its use, were patented and commercialized. This was almost always done by corporations from countries of the north. Profits under this unequal and inequitable system flowed to these corporations. This manner of the misappropriation of resources has been dubbed as 'biopiracy'.

The challenge lies in establishing national regimes that will staunch this misappropriation while allowing for the conservation and sustainable use of these resources; and for the fair and equitable sharing with the providers of these resources. It must also provide for the protection of traditional knowledge which has preserved and enhanced biodiversity; and provides leads for eventual commercial use.

The value

Diversity has produced crops, medicines, clothing and other useful products for humankind. Crops and forages were created in farmers fields over millennia and by research institutes over the last century. This has fed the world. The more distant relatives of these crops and forages are still growing in the wild. They are another source of diversity. These genetic resources have been crucial in the past in producing high-yielding varieties. They are used today in modern breeding, and they will be essential in the future in feeding the world's growing population.¹ There are intellectual property claims over much of the crops developed in modern breeding. The TRIPS agreement of the WTO mandates member countries to provide protection for plant varieties. Malaysia, like so many other developing countries, has put in place a law to fulfill this obligation.² Pharmaceutical companies also produce drugs from genetic materials accessed from the forest and based on leads provided by indigenous peoples and local communities in developing countries. There was no sharing of benefits either with the country or the people. This leakage is significant given that at present a large part of existing medicines in developed countries is derived from natural products collected all over the world.³

Then there is the impetus provided by biotechnology – in particular genetic engineering – whereby biological and genetic resources are manipulated by the insertion of genes foreign to the species. This coupled with the extension of IP rights over genetic materials and life forms allowing for claims over the genes, its sequencing and the progeny, and indeed any product that results from genetic transformation in relation to that resource – has greatly increased the economic value ascribed to genetic resources and traditional knowledge.

In part this IP extension over life forms - achieved by the concerted efforts of the developed countries in securing the revision of the UPOV Convention and the enactment of the TRIPS Agreement - broadened the gap between the source material and improved varieties in terms of value and ownership rights attached to them.

The CBD provides an opportunity to restore the balance. Its benefit-sharing provisions assume an importance in the absence of other protection frameworks, including IPRs. Additionally, the CBD makes a link between access, benefit sharing and IPRs through the recognition that the sharing of IPRs can be a form of benefit sharing.⁴

Developing countries are also relying on the CBD to seek an amendment to the TRIPS Agreement to deal with biopiracy.

¹ Ramantha Rao, 'Effective Strategies in PGRFA Conservation and Utilisation, in *Abstracts Book, National Conference on Agrobiodiversity Conservation and Sustainable Utilisation*, MOA

² New Plant Varieties Act, 2004.

³ See example: Maureen Rouhi, 'Rediscovering Natural Products', 81/41 *Chemical & Engineering News* 77 (13 Oct 2003); Gurdial Singh Nijar, *In Defence of Local Community Knowledge and Biodiversity*, TWN 1996, 4-6.

⁴ Article 16, CBD.

National level

Malaysia ratified the CBD in 1994. It has adopted various policies for the protection of biodiversity. These include: the National Diversity Policy in 1998; the National Biotechnology Policy in 2005; the National Agricultural Policy for 1992 – 2010 and the National Policy on Domestic Animal Diversity. However there has been no law relating to the central features of the CBD – that which relates to access to genetic resources and associated traditional knowledge and the sharing of benefits. This seems also to be the position in many developing countries.

The problems

What has accounted for the lethargy by a large number of developing countries to enact laws that could, after all, earn benefits? In Malaysia, there was a spirited attempt in the late 1990s and a task force drafted a law after extensive inter-agency consultations. But the law was still-born. There were, and are, laws spread over various sectors – forestry, fisheries, agriculture and so on. But none addresses the issue of ABS.

The Constitution distributes power and jurisdiction between the 13 States and the central Federation. Land - on which much of the diversity is located - is on the State List and within the jurisdiction of each State. The initiative for a national law has thus far emanated from the centre. Could this account for the difficulty in promulgating a national law ABS law? This could well be the case. Yet this problem is not insurmountable. For example, there is presently a high powered National Council on Biodiversity and Biotechnology. Its remit is to deal with the issues in this area (biodiversity) to ensure state-federal cooperation. There is precedent for such cooperation. The National Land Code was brought into existence to provide a single code on land matters to replace the different state laws. Such a mechanism can be adapted to laws on ABS. Finally Malaysia has international treaty obligations under the CBD. Treaty-making powers – and the due national implementation and execution of treaties – are the prerogative of the executive. Such executive power is clearly in the Federal list. The States of Sarawak and Sabah have each enacted laws to deal with biodiversity [See appendix 1 of the work of the Sarawak Biodiversity Centre under the law

The context

A law on access and benefit sharing must take into account its international, regional and national obligations. These include:

- The CBD: these state broad goals and obligations for Parties;
- Any regional law – such as the ASEAN Framework Law on ABS;
- Other national laws that deal with genetic resources: in Malaysia there is the new Plant Varieties Act 2004.
- Other international efforts to strengthen the efficacy of the national law: such as the initiatives by developing countries in WTO/ TRIPS, WIPO and the CBD.

A. THE KEY PROVISIONS FOR A NATIONAL LAW

This paper identifies and analyses the key provisions that a developing country must consider for inclusion in a national ABS regime.

1. SCOPE

The following could be considered for inclusion in the scope of the law:

- (a) Genetic material
- (b) Derivatives
- (c) 'Associated TK'
- (d) Resources covered by the International Treaty on Plant Genetic Resources for Food and Agriculture

The further questions to discuss are:

- (i) Whether the regulation should differentiate on the basis of the location of the biological resource?
- (ii) Whether there should be a differentiation based on the user of the resource?
- (iii) Whether there should be any exemptions from the scope?

An Elaboration:

(a) Genetic material

The CBD declares the rights of States over their natural resources. In the context of a law on biological diversity, this term must necessarily mean biological resources. This latter term is defined in the CBD as '*including genetic resources, organisms or parts thereof, populations, or any other biotic components of ecosystems with actual or potential use or value for humanity*'. Thus genetic resources are inherent in biological resources and are a component of these resources. the definition is not exhaustive. The term 'including' suggests that all other matters not covered by the definition can be within the scope of biological resources.

However the obligation to grant access is confined to 'genetic resources'. 'Genetic resources' are defined as '*...genetic material of actual or potential value*'. 'Genetic material' in turn is defined as '*...any material of plant, animal, microbial or other origin containing functions of heredity*'.

What does this term 'genetic material' mean?

(i) *Any material of plant, animal, microbial or other origin*

Any such material can be the source of genetic material and hence a genetic resource. A material accessed for its physical properties not for its genetic material will not be a genetic resource for purposes of the access provision in the CBD. This excludes trees for their value as timber, plants for their value as food or feed and animals for their food value. In modern breeding, biotechnology – in particular gene-technology - uses genetic resources within the biological resource more directly. Gene technology is a technology that transfers genes from one species to another - recombinant-DNA technology. Thus material of this origin used in gene-technology will be covered by the definition as a genetic resource.

(ii) *'...containing functional units of heredity...'*

The material must also contain functional units of heredity. Genes and promoters fall within this category. All cells and therefore all biological material contain functional units of heredity.

(iii) *...of actual or potential value...'*

Genetic resources that are covered by the access provision must be of actual or potential value. 'Value' is not defined. It covers a wide use in common parlance. It could presently or potentially be used for food, feed, propagating material, as input for biotechnological activity, breeding activity, and also have a historic, cultural or ecological value. It may also have an intrinsic value. Given this wide use value, all genetic resources could be considered as genetic material. However, insofar as the actual and potential value relates to the functional units of heredity, this will not cover the use of genetic resource for its biological properties as food, feed and seeds but only in activities where the functional units of heredity come into play.⁵ The definition of genetic resource then does not cover for example agricultural products imported for food or feed.

(iv) *To sum up this view*

Genetic resources are to be understood in the context of the use of biological material. Biological resources are genetic resources when they are used for the purpose of exploiting genes or other functional units of heredity; not for use for their physical properties. The definition of genetic resources excludes the use of biological material when not used for the purpose of its genes. As an example, a seed used for purpose of cross breeding or in developing a new variety is used for its genetic resource. It will be

⁵ *Access and Rights to Genetic Resources: a Nordic Approach*, Nordic Council of Ministers & Nordic Council, 2003, pp. 45-49.

covered by the provision. But not included is a seed that is sown for harvesting for the purpose of use as a commodity. So too, a bull is a genetic resource as a source for fertilizing; not when slaughtered for its meat.

(b) Derivatives

(i) *The importance of including*

Biological resources are accessed not primarily for their physical properties but for information of the use as to their chemical constituents, that is derivatives. This may be the most frequent form of use of a genetic resource. Some of the constituents, once identified, can be synthetically created in the laboratory. It has been said that if derivatives are excluded from the scope, most of the potential value and benefits of adding value to derivatives will be monopolized by large corporations from developed countries. And indigenous and local communities will become the real losers, since in developing countries of origin an important part of TK is related to derivatives.⁶ For this reason the inclusion of derivatives is of considerable importance in an ABS regime. The value of derivatives, especially in the context of genetic engineering, is underlined by the fact that biotechnology is defined in Article 2 of the CBD as, '*...any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use*'.

Developed countries are arguing strenuously for its exclusion from the scope of the International regime on ABS now being negotiated under the CBD. The question then arises: can a national regime legitimately include derivatives within its scope?

⁶ Fernando Casas, 'Genetic Resources and Property Rights. Tangible and Intangible Property Rights. The Issue of Derivatives', in Record of Discussion, International Expert Workshop on Access to Genetic Resources and Benefit Sharing, Cuernavaca, Mexico, October 24-27, 2004, at p. 182.

(ii) *Definition*

Derivatives are defined in various ways: as the chemical constituents of a living organism;⁷ or as 'a molecule, or combination or mixture of natural molecules, including crude extracts of live or dead organisms of biological origin that come from the metabolism of living beings';⁸ or as extracts from biological and genetic resources such as blood, oils, resins, genes and seeds, spores, pollen and the like, as well as the products derived from, patterned on, or incorporating manipulated compounds and/or genes.⁹

(iii) *Article 2 CBD: 'genetic resource' definition includes derivatives*

The term 'genetic resources' in the CBD, as noted earlier, includes any genetic resource – of whatever origin – that contains genes and promoters and which has a present or potential value and is exploited or accessed for its genetic value. This means that any material including its constituent elements – derivatives – are covered by the term. Countries have sovereign rights over these resources and the right to regulate this access. The grant of access to a specific use of the genetic resource or the derivative does not give property rights in the property in the derivative or its inherent biochemical information.

(iv) *In benefit sharing: under CBD*

Article 2 of the CBD does not define genetic resources on the basis of its reproductive functions but on the basis of its composition.¹⁰ All kinds of potential uses of the genetic resource are included; in particular, the use is not restricted to the reproductive capabilities of a genetic resource, such as propagation or using isolated genes. Article 15(7) of the CBD provides that there must be sharing through mutually agreed terms (MAT) of benefits arising from 'the commercial and other utilisation' of genetic resources. 'Utilization of genetic resources' means the use of **any** larger or smaller part, extract or chemical compound from plant, animal, microbial or other origin **containing** genes. This includes the use of derivatives. 'Utilization of genetic resources' would include activities like the production of cosmetics based on the use of plant material, drug development based on the use of marine microorganisms, and, using isolated genes in modern biotechnology.

⁷ Kelly Bannister, 'A Plant Chemist's Perspective on the 'problem' of Derivatives, in Record of Discussion, International Expert Workshop on Access to Genetic Resources and Benefit Sharing, Cuernavaca, Mexico, October 24-27, 2004, at p. 183.

⁸ Decision 391, Article 1, of the Andean Community Law.

⁹ Article 1, ASEAN Framework Agreement on Access to, and Fair and Equitable Sharing of Benefits arising from the Utilization of, Biological and Genetic Resources (as revised 5 August 2004).

¹⁰ The term 'genetic material' is defined by art 2 as any material of plant, animal, microbial or other origin containing functional units of heredity. This includes all elements that are necessary to establish functional units of heredity. This includes genes (including their constituent elements) and the factors that control their expression and their direct products including RNA and protein. So the term 'genetic resource' includes all things contained in and with the genes: Geoff Burton, 'Discussion Paper: Derivatives', in Record of Discussion, International Expert Workshop on Access to Genetic Resources and Benefit Sharing, Cuernavaca, Mexico, October 24-27, 2004, at pp. 185-187.

(v) *In Bonn Guidelines - benefit sharing*

Further the Bonn Guidelines, referred to by the UN General Assembly, the World Summit and COP as the basis upon which to develop an international regime, make it clear that the access and benefit sharing provisions of a material transfer agreement include those arising from the use of derivatives of genetic resources and their products.¹¹ This is based on the fact that the Guidelines include in its scope genetic resources and associated TK and benefits arising from the *commercial and other utilization of such resources*.¹²

(vi) *As a possible element in an International Regime on ABS*

Additionally, COP7's terms of reference for the Working Group on the development of an international regime on ABS – of this more later - requires the issue of derivatives to be considered as an element in the international regime.¹³

(vii) *National law may include*

In any event, countries can include derivatives in the scope¹⁴ of their national ABS law under Article 3 - broad principle of right to exploit resources, or under Article 15 – right to regulate access and benefit-sharing. As an example, the ASEAN Framework Law on ABS requires Parties to include in their ABS laws the disclosure of benefit sharing from biological and genetic resources '*including benefits from derivatives and products arising from the commercial and other utilization of such resources*'.¹⁵

(viii) *Tracking and regulating derivatives in an ABS regime*

A concern has been expressed of the difficulty of tracking the flow of derivatives between laboratories and researchers and its implications for scientific discovery.¹⁶ The problem is presented in these terms. The chemical repertoire of chemical constituents (derivatives) in plants is vast. After the initial field collection and extraction of plant compounds, different laboratories specialize in testing of different medicinal properties. There is a continuous flow of exchange between laboratories of the test results to save time and costs.¹⁷ Companies often approach researchers in medicinal plant labs for their testing results. As a result derivatives move quietly and incessantly between labs, institutions and sometimes countries – through personal or mail delivery. To regulate these exchanges would require tracking the flow of these materials – from scientists to

¹¹ Bonn Guidelines, D. 44.i, and Appendix I, B.2.

¹² Emphasis added. Bonn Guidelines, C.8. See also the use of this phrase in C.16.a.iii, and b.ix. D.41, and D.44.i.

¹³ Decision VII/19, Annex (d)(xii).

¹⁴ See also preceding footnote.

¹⁵ Article 6(2)(h).

¹⁶ Kelly Bannister, 'A Plant Chemist's Perspective on the 'problem' of Derivatives, in Record of Discussion, International Expert Workshop on Access to Genetic Resources and Benefit Sharing, Cuernavaca, Mexico, October 24-27, 2004, at p. 183.

¹⁷ For example, one lab may test for anti-viral properties; another for immune-stimulating activity: preceding footnote, at p. 184.

labs. The implication for an ABS regime is that there must be an effective system for the labeling and tracking of derivatives taking into account the practical realities of the generators and users of these derivatives. This could well be a rather difficult task.

An ABS law will have to take these realities into account. When the plant species is first accessed, then there will be requirement for an access application and the PIC and MAT with the provider of the genetic resource from whence the derivative emanates. The agreement can provide that if there is a use developed subsequently that is different from that shown in the access application, then there has to be a fresh agreement for this new use. Also, that this same condition will attach if the resource is transferred to third parties.

This may need to be bolstered by changes to the patent law as is being proposed by developing countries at international fora. (This is discussed later in this paper.) Invariably before a product is commercialized, a patent is sought. Developing countries at the WTO have proposed changes to the TRIPS agreement to require patent applicants to disclose the source of the derivative, the country of origin, the PIC and the MAT.

(c) 'Associated TK',¹⁸

(i) *The value of TK*

As with derivatives, the traditional knowledge of indigenous peoples and local communities as to the use of the biological resource is what is of value to those seeking access. TK leads researchers to select from amongst the great diversity of plants, animals and microorganisms. It cuts down lead time by as much as a factor of 10. There are numerous examples of this.¹⁹ In 1990, for example, the University of Florida patented a Brazilian fungus known to be lethal to fire ants that can cause more than a billion dollars in damage to US crops. The lead was provided by Brazilian farmers aware that something in the soil kills fire ants. Three-quarters of plants that provide active ingredients for prescription drugs came to the attention of researchers because of their use in traditional medicine.²⁰ Among the 120 active compounds currently isolated from the higher plants and widely used in modern medicine today, 75% show a positive correlation between their modern therapeutic use and the traditional use of the plant from which they were derived.

(ii) *TK included in international fora discussions and regional ABS law*

¹⁸ It has been suggested that 'information' is less ambiguous than 'knowledge' as there is no shared understanding of the latter expression: The Crucible II Group: *Seeding Solutions*, vol 2, IDRC, IPGRI and Dag Hammarskjold Foundation, 2001, at p. 14.

¹⁹ See further: Gurdial Singh Nijar, *Traditional Knowledge and Intellectual Property Interface: Responses, Policies and Options for Developing Countries*, Centre of Excellence for Biodiversity Law, 2007, (forthcoming publication).

²⁰ Kloppenburg, J. Jr., 'No Hunting! Biodiversity, Indigenous Rights, and Scientific Poaching', *Cultural Survival Quarterly*, Summer 1991, p. 15

The inclusion of TK, sometime also described as ‘intangible and immaterial property’, within the scope of the CBD is well recognized among developing countries in the TRIPS debate on making the WTO mutually supportive with the CBD – of which more later. Many regional developing country agreements include TK within the scope of their ABS regimes: as in Decision 391 of the Andean Community on a Common Regime on Access to Genetic Resources,²¹ the Organisation of African Unity Model Law²² and the ASEAN Framework Agreement.²³ The ASEAN Agreement makes clear that access to biological or genetic resource does not automatically include access to the associated TK. Such access must be explicitly indicated in the application for access.²⁴

*TK in National Law*²⁵

An ABS national law will have to provide for the protection of TK. The governing principles should be based on the recognition that:

- TK and innovations are embedded inextricably in the cultural, social, spiritual and economic practices and life of indigenous peoples and local communities. They are generated in this context. Hence TK can only be protected in this contextual form.
- TK is a critical element of indigenous peoples and local communities’ distinct, self-determined, self-identified cultural existence.
- TK must be accorded protection in accordance with the criteria and custom and practices established by the holders of TK;
- TK must also be recognised as a holistic system. Any attempt to reduce it to some component part useful for industry may ultimately lead to its fragmentation and destruction. This could well undermine the cohesiveness of indigenous peoples and local communities.
- Indigenous peoples and local communities must be consulted and participate in all decisions involving their TK. Their PIC must be obtained and they must agree to MAT; they must be able to refuse access or impose conditions where appropriate, such as where access is to their sacred or culturally sensitive knowledge or where it would impinge affect their lifestyle and traditions – especially in relation to the conservation and use of biological diversity.
- The integrity of TK should be insulated from being undermined by IPRs.

²¹ See also Decision 486, Article 14.

²² The African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources.

²³ ASEAN Framework Agreement on Access to, and Fair and Equitable Sharing of Benefits arising from the Utilisation of Genetic and Biological Resources, Rev. 5 August 2004, Article 4(1)..

²⁴ Article 4(1).

²⁵ See further: Gurdial Singh Nijar, *Traditional Knowledge and Intellectual Property Interface: Responses, Policies and Options for Developing Countries*, Centre of Excellence for Biodiversity Law, 2006, (forthcoming publication).

(d) Resources covered by the International Treaty on Plant Genetic Resources for Food and Agriculture

This treaty, negotiated and concluded under the UN Food and Agricultural Organisation (FAO), deals with plant genetic resources for food and agriculture (PGRFA).²⁶ It establishes a multilateral system for access and benefit sharing of genetic resources for food and agriculture as specified in a list in Annex I – consisting of 35 crops and crop complexes and 29 forage species.²⁷ The list can be expanded by consensus of the Parties to the FAO. Not all crops on the list are automatically included in the multilateral system. Only those crops for which some PGRFA are **under the management and control of the Contracting Parties** and are **in the public domain** are included.²⁸ Under Article 12 of the Treaty, the Parties agree to take the necessary legal or other appropriate measures to provide facilitated access through the multilateral system to other contracting Parties and to legal and natural persons under their jurisdiction. The Article sets out the terms and conditions applicable for such access. These include the important condition that access will be provided solely for the purpose of utilization and conservation for research, breeding and training for food and agriculture.

Malaysia acceded to the Treaty on 5th May 2003. By ratifying the Treaty, a country exercising its sovereign right to determine access to genetic resources in accordance with Article 15 of the CBD, gives its general prior informed consent (PIC) to access to the species listed in the annex of the Treaty. The mutually agreed terms (MAT) of such access are those that will be set out in the standard material transfer agreement (MTA) that has been developed by the Parties to the Treaty. Recipients of materials through this multilateral system cannot claim IPR or other rights that limit facilitated access to PGRFA or their genetic parts or components.

Hence a national law on ABS must state that

- The scope covers such of the listed plant genetic resources that Malaysia declares to be under its management and control and are in the public domain;
- The need for access approval, and the conditions for access.
- Access will be provided solely for the purpose of utilization and conservation for research, breeding and training for food and agriculture;
- Access is subject to PIC as specified in national law ;
- The PIC for the access is deemed granted, on the terms set out in the Treaty; and

²⁶ It came into effect on June 2004.

²⁷ Not included are some crops of great value to sustainable agriculture and food security such as: soya bean, groundnut, many fruits and vegetables and tropical forages. Others that are not so widespread include: African leafy vegetables which are potentially important as they provide nutritional well being of the populace of many developing countries and regions.

²⁸ Gerald Moore and Witold Tymowski, *Explanatory Guide to the INPGR-FA*, IUCN, 2005, at p. 15 (emphasis as in original). The ensuing discussion is also based on this source.

- The benefit sharing arrangements are as set out in the MTA.
- No IPR or other rights can be claimed by the recipients of the genetic resource or their genetic parts or components.²⁹
- The genetic resources should not be given to third parties unless under these same terms. This includes keeping these resources in the public domain.

(e) Resources based on ownership: public or private

Where resources are on public land, the right of the State to regulate access to them is clear. What if the genetic resource is on land that is privately owned? The land laws of many countries extend ownership rights to whatever is on the land as well. Who will be the provider of these resources? It is noted that the CBD gives countries the right to regulate access to *genetic* resources on the basis that this belongs to the State.

(i) *Options*

There are three possible options:³⁰

First, that the proprietary rights to biological material only implies a non-exclusive *right to use* the genetic resource.

Secondly, these proprietary rights to biological material only implies non-exclusive *rights to such material*.

Thirdly, rights to genetic resources are separate from ownership over biological resources. The private property rights to the biological materials are still respected but the granting of rights to the genetic resources is left to national legislation.

(ii) *The Andean Community position*

The Andean Community – Bolivia, Columbia, Ecuador, Peru and Venezuela – genetic resources and derivatives are public property and inalienable. These resources can neither be bought nor sold. There are no private property rights over the tangible or intangible components of these resources.³¹ The resources are said to be the ‘public patrimony of the nation’.

²⁹ Some proposals add the words: *...in the form received*: *Access and Rights to Genetic Resources: a Nordic Approach*, Nordic Council of Ministers & Nordic council, 2003, at p. 111.

³⁰ *Access and Rights to Genetic Resources: a Nordic Approach*, Nordic Council of Ministers & Nordic council, 2003, at pp. 116-117.

³¹ Fernando Casas, ‘Genetic Resources and Property Rights. Tangible and Intangible Property Rights. The Issue of Derivatives’, in Record of Discussion, International Expert Workshop on Access to Genetic Resources and Benefit Sharing, Cuernavaca, Mexico, October 24-27, 2004, at p.178.

In the Andean Community law scenario, the land owner's right to possession of a resource is recognized where the resource is found on his land if he can establish that he has been conserving the intrinsic value of biodiversity and the ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic values of the resource. Once this right to possession is established, then the owner's PIC must be obtained for access to the resource; and he is entitled to a share of the benefits. The private owner/supplier of the resource must not undermine the national interest or patrimony; and must comply with Decision 391 that regulates access to genetic resources and derivatives.³²

This implies that the sovereign rights to the genetic resource lies with the State. However the limited rights of owners of private lands where the resource is found are recognized. They have the right to the non-exclusive use of the biological resource. As regards indigenous peoples and local communities, there should be a presumption that they are in possession of the resources in this sense. For others, if they can establish that they have been conserving the intrinsic value of biodiversity and the values as outlined above, then:

- The owner's PIC must be obtained;

This cannot be unreasonably withheld given the right of the State to grant access to genetic resources and derivatives within its jurisdiction;

- The owner is entitled to a fair share of the benefits.

(iii) *National law options*

A national law may consider the inclusion of the following scope:

- Biological resources, including genetic resources and their components, found in *in-situ* conditions and their derivatives;

For purposes of access and benefit sharing:

- The PIC of the person in possession of the biological resource must be obtained;
- The PIC of indigenous peoples and local communities occupying/owning land where the resource is to be accessed must be obtained;
- A definition of 'person in possession' (to consider the inclusion of some features of the Andean Community formula).
- In any event the access and PIC of the State must be obtained in addition to the PIC of the person in possession and indigenous peoples and local communities involved.³³

³² As in preceding footnote.

³³ The Philippines' Executive Order 247 require the consent of both the government and the local communities involved.

- (f) Based on the users of the resource: commercial or non-commercial (researchers in public institutions)

Is there a basis for distinguishing between the various users of the resource? In particular, should non-commercial researchers be exempted from the access provisions? Perhaps a case can indeed be made out for exemption from the access provisions for this category especially for work in public institutions. However this has to be carefully considered. Where lies the boundary between the commercial and non-commercial research, and who will draw this line?

The line between research for commercial purposes and non-commercial purposes is blurring.³⁴ It is not uncommon, especially in a developing country context, for the private sector to fund public research with the expectation of commercializing the research result. Or the research is jointly undertaken. In the US the Bayh-Dole Act of 1980 sought to permit IP claims over outcomes of federally sponsored research. Universities and other public research organizations responded by aggressively pursuing IPR protection to generate revenue. The OECD promotes this model to turn 'Science into Business'.³⁵ This kind of collaboration is also the avowed aim of most public universities in Malaysia.

- (g) Exemptions from the scope

A national law may wish to specify what is, and who are, exempted from the scope of the access requirements. This is not the same as saying that the subject matter is not within the scope of the law.

One such exemption is the traditional uses of biological and genetic resources by indigenous peoples and local communities in accordance with their customary practices and traditions.

The other is the prohibition of human genetic resources from being the subject of access applications. Technically human genes may qualify as genetic resources within the meaning of the CBD. COP2 of the CBD made it clear that they were excluded. Nonetheless it may be prudent to provide for its express exclusion.

Both these exemptions are incorporated in Article 4 of the ASEAN Framework Agreement.

³⁴ See example: Royal Society, *Keeping Science Open: The Effects of IP Policy on the Conduct of Science*, London Royal Society, 2003: www.royalsoc.ac.uk/files/statfiles/document-221.pdf.

³⁵ Cited by Paul Oldham, *Global Status and Trends in IP Claims: microorganisms*, ESRC Centre for Economic and Social Aspects of Genomics, 2004, at p. 16-17.

2. ACCESS

(a) Applications for access: competent authority, powers, procedure for applications

A State in the exercise of its sovereign rights will regulate access to all resources within its territorial jurisdiction. This implies the need for an application for access. Any access without permission will be illegal. An access infrastructure must be set up by national law. There must be constituted a national competent authority to receive and process applications. The role and functions of this authority will have to be delineated. Beyond the usual role, it may be given additional functions even where it is not the owner of the resource. This may include: to negotiate on behalf of the State or other parties, track genetic resource use, collect and disburse fees and other benefits, enforce agreements and coordinate collections and deal generally with all matters relating to the access. Other matters may include the procedure for the applications; the right to appeal against any refusal for access or the conditions imposed, and the penalties for unauthorized access.

(b) Who is the authority to grant access: the country of origin?

As States have sovereign rights over their resources, they will have the power to grant access. They will be the provider of the genetic resource. This refers to Parties to the CBD that are the countries of origin of these resources; or countries who have acquired the genetic resources in accordance with the CBD.

The expression 'country of origin is defined as ...*the country which possesses those genetic resources in in-situ conditions*'. For species that are not domesticated or cultivated, *in-situ* conditions are '*where genetic resources exist within ecosystems and natural habitats*'. This means the country where the resources are found naturally. For domesticated or cultivated species the conditions are '*...the surroundings where they have developed their distinctive properties*'. This will include a resource acquired from another country, which then adapts, or is developed, to have a distinctly different genetic make-up from the original genetic resource. So Malaysia will be the country of origin of palm oil or rubber if these resources can be shown to have been developed over the years by Malaysia and have developed genetic characteristics that are different from the materials acquired historically from the source countries.

The other limb of the definition of 'country of origin' is a country that has acquired the resource in accordance with the CBD. Treaties do not, as an accepted rule of interpretation, have retrospective effect.³⁶ This means that the CBD only applies to collections made after the coming into force of the CBD. Again, if the genetic material is acquired contrary to the provisions of the CBD even after the coming into force of the CBD, it will be excluded as it has not been acquired in accordance with the CBD.

³⁶ Article 28, Vienna Convention on Treaties.

218

In respect of resources on private lands or lands occupied by indigenous peoples and local communities, there may also need to be an additional tier for consent as discussed earlier.

(c) The obligation

The obligation under the CBD is to create *conditions to facilitate* access. This means no more than putting in place a legislative or administrative regulatory framework that sets out clear provisions as to how, and on what terms, access can be obtained.

(d) Imposing conditions for access

(i) *For environmentally sound uses*

The access can be made subject to conditions. First it should be for environmentally sound uses: Article 12. This term is not defined. It could mean adverse impacts to biological diversity, centres of habitats, centres of origin, and traditional knowledge and practices. Article 14(1)(a) of the CBD refers to '*procedures requiring environmental impact assessment of ... proposed projects that are likely to have significant adverse effects on biological diversity...*'.

(ii) *No undue restrictions that may undermine CBD's objectives*

Secondly, the word 'facilitate' suggests that there should be no undue and cumbersome restrictions that would in effect undermine a genuine applicant. In particular, there should not be any restrictions that undermine the objectives of the CBD. The objectives are threefold:

- The conservation of biodiversity;
- The sustainable use of its components;
- And the fair and equitable sharing of the benefits arising from the utilization of the genetic resources.

(iii) *Denial if access may undermine CBD's objectives*

Thirdly, and conversely, this also means that access may be legitimately refused if it results in any of the objectives being undermined. For example, if the collection of the genetic resource could undermine the sustainable use of the components of biodiversity, access may be denied or given subject to conditions to minimize or avoid the adverse impacts. This may also authorize a State to require an assessment of the impact of the bio-prospecting on any of the objectives of the CBD. Article 14(1)(a), cited earlier, contemplates such impact assessments.

The Andean Communities' law on access³⁷ provides the following situations when access may be partially or entirely refused:

- Endemism, rarity or danger of extinction of species, subspecies, varieties, or races or breeds;
- Vulnerability or fragility of the structure or functioning of the ecosystems that could worsen as a result of access-related activities;
- Adverse effects of access-related activities on human health or on elements essential to the cultural identity of nations;
- Undesirable, or not easily controlled, environmental effects of access-related activities on the ecosystems;
- Risk of genetic erosion caused by access-related activities;
- Regulations on biosafety, or on genetic resources and their derivatives or geographic areas rated as strategic.

(iv) *Access must be consistent with the sustainable use of the components of biodiversity*

Again access is for sustainable use of the components of biodiversity. The Andean Community's list of situations when access may be refused includes that where access may undermine sustainable use. According to a set of Guidelines developed by the IUCN in developing the concept of 'sustainable use of the components of biodiversity', the use of a particular species is likely to be sustainable if:

- a. it does not reduce the future use potential of the target population or impair its long term viability;
- b. it is compatible with the maintenance of the long term viability of supporting and dependent ecosystems; and
- c. it does not reduce the future use potential or impair the long term viability of other species.

Other considerations that should be taken into account are avoiding wasteful use and protecting animals from cruelty and avoidable suffering. Although the Guidelines are primarily for wild species, they are considered holistic in nature as they cover species and ecosystems. Thus Guideline (a) focuses on the impacts to the species being used. Guidelines (b) and (c) weigh a particular species use against the impacts the use has on ecosystems and other species.³⁸

³⁷ Decision 391, Article 45. Fernando Casas, 'Genetic Resources and Property Rights. Tangible and Intangible Property Rights. The Issue of Derivatives', in Record of Discussion, International Expert Workshop on Access to Genetic Resources and Benefit Sharing, Cuernavaca, Mexico, October 24-27, 2004, at p. 181.

³⁸ Lyle Glowka and others, *A Guideline to the Convention on Biological Diversity*, IUCN, 1994, at p. 57. The Guidelines referred to are: Guidelines for the Ecological Sustainability of Non-consumptive and Consumptive Uses of Wild Species.

These Guidelines may be incorporated in national law to restrict or limit access.

(v) *Other conditions*

Other conditions consistent with the objectives of the CBD may be imposed. These could include, if there be any collection or other form of access, such conditions as a declaration of: the purpose of the collection, the amount, the area, the duration, the collaboration of nationals in the access activity, the anticipated benefits, the nature of the rights to be claimed, what is to be done with the material or information accessed, whether research results will be shared, plans for cooperation with nationals in the R&D.

(e) *Terms of the access*

The CBD provides that access where granted shall be:

- a. on mutually agreed terms (MAT): Article 15(4);
- b. subject to the prior informed consent (PIC) of the provider country: Article 15(5); and
- c. on terms that include a fair and equitable sharing of the benefits: Article 15(7).

3. **MUTUALLY AGREED TERMS - MAT**

The law must establish the procedure for MAT. This will invariably be by agreement. The state can leave parties to negotiate the terms as it is usual to expect that the provider will be approached by a commercial entity for access. However there may be situations where the resource provider (say a local community) is unmatched in terms of resources and competence with a user (say a large company). In such a case, the law may prescribe a standard MAT agreement which contains the essential minimum safeguards. Or require the intervening guiding hand of the State through the designated competent authority.

The State would be the primary party where it owns the resources. Where others are the owners, MAT must be entered into with the holders of that resource as discussed earlier as well as the State. There could be a tripartite agreement: the provider (State), the owner and the applicant. Or, as an alternative there may be a provision for the State to review all agreements and indicate its approval of the agreement. This may be necessary as the State is ultimately responsible, at the international level, for ensuring that there is no breach of its obligations under the CBD.

MAT should generally precede PIC. 'Informed' consent implies a full knowledge of the access, its impact and the benefits. This suggests that PIC will only be given if the terms are mutually acceptable and agreed upon. Indeed a MAT agreement can be more appropriately merged within the PIC procedure.

4. PRIOR INFORMED CONSENT - PIC

Prior informed consent will:

- require the applicant to obtain affirmative consent of the provider(s);
- be based on complete relevant information and full disclosure.

Again the provider whose consent must be obtained is to be determined by reference to the ownership of the genetic resource. How this is determined, has been discussed earlier in the context of the scope of a law on access. The law must stipulate the procedure for obtaining PIC. The kind of information to be supplied that may have a bearing on whether access should be given must also be stated. Such information could include: the implications of the access, the nature of the genetic resource to be used – whether tangible or not, the quantity of the resource to be accessed, how and by whom the resource will be later used.

Unlike MAT, PIC is optional as made clear by the expression ‘unless otherwise determined by the Party’ in Article 15(5) of the CBD. This means that a State must affirmatively provide for this requirement, otherwise PIC is not required. Also, a State has the option of excluding, or limiting the situations for, the PIC requirement in its law.

5. FAIR AND EQUITABLE SHARING OF BENEFITS

This requirement is interlinked with the first two. For only if MAT include fair and equitable benefit-sharing arrangements will PIC be given. Article 15(7) of the CBD requires the sharing to be upon MAT. The sharing is of:

- The results of R&D; and
- The benefits arising from the commercial and other utilization of the genetic resources accessed.

The paragraph refers to articles 16 and 19. This expands the coverage of the benefits to:

- Access to and transfer of technology using those resources including technology protected by patents and other IPRs: Article 16(3);
- facilitated access to, joint development and transfer of technologies (including biotechnologies) that are relevant to the conservation and sustainable use of biodiversity, or that makes use of genetic resources: Article 16(2) and (1);
- Participation in biotechnological research: Article 19(1); and
- Priority access to the results and benefits arising from biotechnologies using the resource provided: Article 19(2).

There are a range of possible benefits that can be negotiated in MAT. These could include: monetary benefits such as upfront fees, royalties, advance payments, sample fees, access to technology.

A law could simply state that fair and equitable benefits be provided for in a MAT. Then it is for parties to negotiate the terms. The law could also go further and make some benefits mandatory and others subject to agreement between the parties to MAT. For example, if a country thinks it important to develop its technological base, the law could require that all R&D activities must involve local participants and the results shared.

Also as the result of the use may not be known at the time MAT is negotiated, it will be prudent for the law or the MAT to require that the use of the resource be declared; and that if the use is other than the declared use, then the benefits are to be mutually negotiated and agreed upon subsequently. This requires provisions that oblige the user to keep the provider informed of the research and use of the genetic resource and its use for a different subsequent purpose. The law may also provide for the PIC of the provider before the resource is transferred to a third party. This will enable the negotiation of MAT with the new party.

The law or MAT should also provide for: the potential benefits (including any IPRs), how the benefits are to be distributed and who is to own the samples.

B. NATIONAL LAW: NEW PLANT VARIETIES ACT 2004

Malaysia has enacted a law on new plant varieties in 2004. This was in response to the requirement in Article 27(3)(b) of TRIPS for members to provide for the protection of plant varieties.

PIC

Applications for the registration of new plant varieties must:

- be accompanied with the written consent of the local community or indigenous people if the variety is developed from traditional varieties;
- give information relating to the source of the genetic material or the immediate parental lines;
- give evidence of compliance of any law regulating access to genetic or biological resources; and
- provide information that there has been compliance with any biosafety law in cases where the variety involves genetic modification.

The Act envisages the role of an ABS law as the application for a plant variety registration (PBR) must also be supported by documents that comply with any law dealing with access to genetic or biological resources. This provides an opening to ensure

that appropriate benefits accrue to farmers and the country from the use of farmers' TK and innovations in plant breeding. One of the objectives of the Act is to provide for the 'recognition and protection of (the) contribution made by farmers, local communities and indigenous people towards the creation of new plant varieties'.

As the New Plant Varieties Act is already in force, this underlines the urgent imperative for a comprehensive national law on ABS.

II. INTERNATIONAL DEVELOPMENTS

Developing countries are concerned that national measures are insufficient to stem the biopiracy of their biological and genetic resources and associated TK primarily through IPRs. They have made proposals to deal with this problem at international fora. A national regime will have to consider whether the proposals will indeed reinforce national ABS laws; and consider how to incorporate these in national legislation.

A. WTO/TRIPS

(a) The proposals of developing countries at the WTO/ TRIPS Council

In May 2006, nine developing countries presented a proposal to amend the TRIPS Agreement³⁹ – in particular Articles 27.3 and 29.⁴⁰

The proposal requires any application for a patent to:

- disclose the source and country of origin of the genetic resources including the TK used in the invention;
- provide evidence that the country of origin had consented to its extraction and use; and
- furnish evidence of fair and equitable sharing of benefits under the national regime.

These requirements must be stated in a certificate from the country of origin accompanying the application for a patent – known as 'a certificate of origin'.

³⁹ Brazil, India, China Pakistan, Peru, Thailand and Tanzania. A revised version adds China and Cuba as cosponsors. WT/GC/W/564.

⁴⁰ The TRIPS Agreement is understood as permitting members to introduce an obligation to disclose the origin of genetic resources and TK in patent applications. This proposal obliges members to introduce a mandatory obligation. Hence the need for an amendment.

- (b) The rationale offered: need for international obligations to supplement national regimes ⁴¹

Developing countries say that their proposals, if accepted, would implement TRIPS and the CBD in a mutually supportive way. Also it would deal with the problem of biopiracy. As bio-piracy transcends borders, they argue, it requires an effective global solution.

National laws requiring ABS and prior informed consent in their patent and other laws has a limited territorial reach. National regimes have no control over resources acquired from their country in respect of which patents claims are then made in another country over that material or inventions deriving from that material. It is necessary then to have universally binding provisions mandating countries to enforce measures against such misappropriation through their national patent laws and to ensure that the provider countries are not deprived benefits. Such binding requirements would supplement measures in national regimes and ensure patent applicants comply with the laws and practices of the countries of origin of the genetic resources including associated TK, in accordance with the objectives and norms of the CBD.

A recent paper commissioned by the Secretariat of the CBD acknowledges the validity of this argument. It states that while the CBD places the responsibility of ABS on both the user and the source provider, yet the national legislation of both developed and developing countries emphasises almost exclusively on access to the genetic resources of the provider country. The paper notes that little relevant user laws have been adopted:

At present, developed country legislation does not appear to address the separate requirement of the adoption of legislation or other measures with the aim of sharing in a fair and equitable way ... the benefits arising from the commercial and other utilization of genetic resources as required in Article 15.7. It is certainly perceived not to support any attempt to enforce ABS requirements of source countries. Claimants seeking remedies or enforcement of ABS principles in these countries, would be forced to use basic provisions of contract and property law, which evolved centuries before any concept of genetic resources as property, and which do not provide any legal basis for ABS actions'.⁴²

So far the response to the proposals from the developed countries has been mixed. The US, in particular, sees no conflict between the CBD and TRIPS, and argues that CBD obligations can be satisfied by taking action at the national level, without the need for action to be taken on the patent system or at the WTO. The US argues that these

⁴¹ For a background to the emergence of these proposals see: Gurdial Singh Nijar, Legal Issues and Frameworks relating to Access and Benefit Sharing of Biological Resources in Malaysia: current status and future needs, pending publication in Proceedings of the National Conference on Agrobiodiversity Conservation and Sustainable Utilisation, 2007; see further, Gurdial Singh Nijar, *Traditional Knowledge and Intellectual Property Interface: Responses, Policies and Options for Developing Countries*, Centre of Excellence for Biodiversity Law, 2007, (forthcoming publication).

⁴² UNEP/CBD/WG-ABS/4/INF/6, IUCN-Canada, *Analysis of Claims of 'Unauthorised Access and Misappropriation of Genetic Resources and Associated TK'*, IUCN-Canada, 2005, at p. 28.

requirements are extraneous to the criteria for establishing the grant or refusal for a patent – namely, that the patent is new, involves an inventive step and has industrial utility.

The European Union is prepared to consider the proposals of the developing countries but only as a basis for discussion. It does not agree with the proposals requiring disclosure of evidence of prior informed consent and benefit sharing. It is also against any form of penalties under patent law. In other words, it agrees only with the disclosure of the country of origin.

A large number of countries support the continued discussion on disclosure, and are agreeable to the suggestion that the future meeting discuss the form and content of the proposals.⁴³

These negotiations need to be closely monitored. If the amendments are carried, then these will have to be reflected in the national law on ABS. There may also be a need then to amend the national patent law to impose conditions for the processing of patent applications.

B. CBD: ESTABLISHING AN INTERNATIONAL REGIME ON ACCESS AND BENEFIT SHARING (ABS)

Yet another development that has to be closely monitored is the negotiations for an international regime on access and benefit sharing. This is being sponsored by developing countries to bolster national ABS laws. This is premised on the view that the PIC, MAT and the benefit-sharing provisions in Article 15 would not be effective unless there are binding international measures to ensure that access is in compliance with the national law of the provider country; and that there is a fair and equitable sharing of benefits of the commercialization and utilization of the resource.

1. COP 7 DECISION; WORKING GROUP; COP 8 DECISION

On the basis primarily of the exhortations by the World Summit and the UN General Assembly resolution,⁴⁴ the 7th meeting of the Conference of the Parties in Kuala Lumpur in 2004 – COP7 - set in motion negotiations for an International Regime (IR) on access and benefit sharing of genetic resources. It established a Working Group and agreed on the terms of reference. The scope of the potential IR includes access, and promoting and safeguarding of fair and equitable sharing of benefits in accordance with the CBD provisions; also included within the scope are: TK, innovations and practices in accordance with Article 8(j) of the CBD. Among the elements in the terms of reference

⁴³ The Report of the last TRIPS Council of the WTO agreed that the 'work (on the relationship between the TRIPS and the CBD) continue on the basis of para 19 of the 2001 DOHA Ministerial Declaration and the progress made in the Council for TRIPS to date': S. Shashikant, 'TRIPS transition period for LDCs extended by 7.5 years with conditions', *Third World Economics*, TWN, issue 368, 1-15 Jan 2006, 21 at 22.

⁴⁴ For details see gurdial singh Nijjar, footnote 41.

are: measures to ensure the prior informed consent of indigenous and local communities holding TK associated with genetic resources; internationally recognized certificates of origin/source/legal provenance of genetic resources and associated TK; disclosure of origin/source/legal provenance of these in applications for IPRs; and the recognition and protection of the rights of indigenous and local communities over their TK associated with genetic resources and 'subject to national legislation'.

COP8 held in Brazil in March 2006, agreed to continue negotiations on the IR on the primary basis of a text produced by the working group at Granada. The next round of negotiations is scheduled for 10 – 14 September 2007 and will be followed immediately by a meeting of the Article 8(j) WG. It is agreed that the negotiations be concluded 'as soon as possible and in any event no later than COP 10 scheduled for 2010'.

These negotiations will have to be closely monitored as a national ABS law will have to take into account the terms of an IR.

(a) Disclosure requirements

The COP8 decision highlights, as a possible measure for the development of the international regime, the disclosure of origin/source/legal provenance of genetic resources in IPR applications in national jurisdictions, in accordance with Art 16(5) of the CBD. It was decided that a group of technical experts be nominated. They are to meet and prepare a report on the form, intent and functioning of an internationally recognized certificate of origin/source/legal provenance. The group is to look at the usefulness of the certificate in fulfilling the objectives of the CBD, in particular Articles 15 and 8(j). The issue of the desirability of this certificate is left open. The group is expected to meet on 22 – 25 January 2007.

(b) Cooperation with the Working Group (WG) on article 8(j)

Also to be closely watched is the work of the working group dealing with rights of TK of indigenous and local communities.

COP7 has tasked this working group on Article 8(j) of the CBD to consider non-intellectual-property based *sui generis* forms of protection of TK; as well as to develop elements for *sui generis* systems for TK listed in an annex of 'some potential elements'.⁴⁵ These include: recognition of elements of customary law relevant to the conservation and sustainable use of biodiversity with respect to: customary rights in TK, biological resources and customary procedures for access and consent to use TK, biological and genetic resources; a process and set of requirements governing PIC, MAT and equitable sharing of benefits with respect to TK; rights of TK holders and conditions for the grant of the rights; the rights conferred; a system for the registration of TK and systems for the

⁴⁵ Decision VII/16H in *The 2010 Biodiversity Target, Decisions from COP7*, UNEP, 2004, p. 227, para 6.

protection and preservation of TK; provisions for enforcement and remedies; relationship to other laws, including international law; and, extra-territorial protection.

Through these 2 Working Groups, a clear basis has been established for developing countries to press ahead with their agenda of establishing regimes at the international level to deal comprehensively and effectively with the misappropriation of TK and GR as well as provide for the sharing of benefits. And to ensure that the international regime developed is consonant with the recognition and protection of TK. Central to these efforts will be a satisfactory resolution of the interface between TK and IP. Realistically this will only be possible if indigenous and local communities are actively involved in the development of the regime.

C. WORLD INTELLECTUAL PROPERTY ORGANISATION - WIPO

Proposals similar to those suggested at the WTO/TRIPS have been introduced in WIPO by developing countries. These are referred to as 'the development agenda. This includes proposals for the protection of traditional knowledge, traditional cultural expressions (folklore) and genetic resources. They are part of a multi-pronged approach in all fora dealing with patents for a uniform stance with regard to effective international measures to combat misappropriation. Negotiations over these proposals ended in a stalemate at the last meeting of the intergovernmental committee held in June this year – 2006 - over whether to address substantive legal text before completing work on objectives and principles. The arguments for and against are much the same as in WTO/TRIPS.⁴⁶

III. ISSUE: DISCLOSURE OF COUNTRY OF ORIGIN

There is concern amongst developing countries that including disclosure requirements for patent applications will mean that they will have to disclose the country of origin from where it originally took its genetic resources such as palm oil and rubber. They fear that it may then have to fork out huge payments as benefits it has reaped through the commercialization of these commodities.

It is submitted that this fear, with respect, is unfounded for the following reasons.

First, the amendments to make mandatory the disclosure requirements at the WTO are to make the WTO provisions compatible with the CBD provisions relating to access and benefit sharing of genetic resources and associated TK. More specifically it is to ensure that the WTO does not undermine the access and benefit sharing provisions in article 15 of the CBD. The genetic resources in this article are confined to those that the Parties have acquired 'in accordance with this Convention': Article 15.3 CBD. This will exclude two distinct cases:

⁴⁶ See earlier footnote 41.

- Resources acquired prior to the Conventions' entry into force from the provider of the resource; and
- Resources acquired illegally from the country of origin after the Convention's entry into force.

The first case reflects the principle that international agreements do not have retroactive effect.⁴⁷ This means that resources acquired before the CBD entered into force are excluded from the reach of articles 15, 16 and 19. Hence no legal claims can be made by Parties for benefit sharing.⁴⁸

Secondly, under the CBD, the country of origin regulates access rights and is entitled to the benefits. 'Country of origin' is defined as the country which possesses those genetic resources in *in-situ* conditions, that is, within the country's ecosystems and habitats. 'Habitat' is defined as the place or type of site where an organism or population naturally occurs.⁴⁹ In the case of domesticated and cultivated species *in-situ* conditions means the surroundings where the genetic resources have developed their distinctive properties.⁵⁰ This refers to the country where the genetic resource has developed its distinctive properties.⁵¹ Where can a gene be said to have developed its distinctive properties? Rubber and palm oil in Malaysia, for example, were brought from Brazil and Africa respectively during colonial rule. Over the years these resources have been developed. I have been advised that our palm oil and rubber since 1994 in any event, has acquired distinctive properties. If this distinctiveness can be established, then Malaysia will be the country of origin and is entitled to require other countries to disclose in patent applications this fact and to prove they have PIC, MAT and benefit sharing arrangements before their application for a patent will be processed or granted. Malaysia then stands to reap the benefits.

Thirdly and, more importantly, countries from where the resource were first taken accept the fact that the CBD does not cover these resources; as well as the fact that these resources 'belong' to the country where they have developed distinctive features.⁵²

Fourthly, the requirement for disclosure only applies in applications for patents. If no such application is intended to be made, the disclosure provisions will not, in any event, apply.

Fifth and finally, the disclosure requirement in patent applications is a mechanism to prevent its unauthorized use and ensure the sharing of benefits. It does not apply where there is no intention to misappropriate the resource, and proper bilateral arrangements are made for access and commercial use of the resource.

⁴⁷ This is a principle of interpretation: see article 28 of the Vienna Convention.

⁴⁸ Lyle Glowka et al, *A Guide to the Convention on Biological Diversity*, IUCN, 1994, pp. 77, 79.

⁴⁹ Article 2 CBD.

⁵⁰ Article 2 – defining 'country of origin' and 'in-situ conditions'.

⁵¹ Lyle Glowka et al, *A Guide to the Convention on Biological Diversity*, IUCN, 1994, p. 18.

⁵² This is the position taken by the Group of Megadiverse Countries at the negotiations for the International Regime beginning with the Working Group meeting in Bangkok in early 2005.

IV. ABS AND IPRS

An ABS agreement needs to deal with the commercialization and IPR claims over the product that uses genetic resources and associated TK. The disclosure requirements sought by developing countries in international forums are to ensure mutually agreed benefit-sharing arrangements between the provider and the applicant. Recently concluded contracts in countries even without an ABS regime have addressed the issue of ownership of the resource and the consequent benefit sharing arising from the commercialisation of the product.

For example, Samoa recently concluded an agreement with the University of California to isolate from an indigenous tree the gene for a promising anti-AIDS drug. The bark and the stem-wood of the *mamala* tree naturally produces *Prostatin*. The discovery of its anti-viral properties is based on traditional Samoan plant medicine. Traditional healers first taught American ethnobotanists how to use the plant. It is intended to clone the genes and insert them in bacteria to make microbial factories for the drug. The agreement acknowledges sovereign rights in the gene sequence of Samoa. Fifty percent share of the commercial proceeds from the genes will be allocated to the government, to villages and to the family of the healers who gave the know how for extraction.

Ethiopia early this year (April 2006) concluded an agreement with a Netherlands company, giving it exclusive access to an agreed list of *Teff* varieties to be used for producing *Teff*-based food (flour and bread mix) and gluten-free beverage products (beer and distilled products) and to develop new varieties of the plant more suitable for producing such products. The company is not permitted to access the TK of the communities on the conservation, cultivation and use of *Teff*. It has agreed not to claim any rights of such TK nor make any commercial benefits from it. The Ethiopian Institute will inform the company of the existing TK that is relevant to the research proposed by the company. This is to 'avoid possible confusion' between the TK of local communities and inventions made by the company. The company has also agreed not to claim IPRs over the genetic resources of *Teff* or over any component of the resources. But it is allowed to obtain plant variety protection over the varieties it develops as co-owners with the Ethiopian authorities. There is provision for non- monetary and monetary benefits, including royalty payment of the profit from the sale of basic and certified seeds of the *Teff* varieties specified.

A similar agreement was entered into between Ethiopia and a UK Company with regard to *Vernonia* - an annual industrial oilseed crop containing about 42% oil. Although the company cannot claim IPRs over *Vernonia* or over any of its genetic components, it has the right to obtain IPRs 'relating to inventions, products or applications developed using *Vernonia* oil'. Other differences include: the company need not share the research results if they affect the commercial advantage of the company. It is left to a future agreement to specify what it is that affects the company's commercial advantage. The company is described as having 'certain intellectual and industrial property rights to a novel oil

extraction and refining technological know-how potentially relevant to the development of products derived from the oil'.⁵³

An ABS law may include a provision specifying that the issue of IPRs be addressed and considered. It could, for example, require the following to be considered: can IPRs be claimed in respect of the genetic resource and associated knowledge, can such rights be claimed for the innovation based on the resource and the knowledge, how are the benefits to be shared on commercialization of the product/innovation?

This way benefit sharing may indeed be a strategy for rebalancing the current imbalances in the IPR regime.⁵⁴

V. IMPLEMENTING THE ASEAN FRAMEWORK AGREEMENT ON ACCESS TO, AND FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THE UTILISATION OF, BIOLOGICAL AND GENETIC RESOURCES: AS REVISED ON 5 AUGUST 2004

Malaysia and Indonesia along with 7 other countries are members of ASEAN. ASEAN has finalised the final draft of the above agreement on 5 August 2004. No party has signed the agreement as yet. The agreement comes into force 60 days after the 6th Party ratifies the agreement. Singapore and Philippines have indicated their readiness to sign the agreement.

Introduction

The agreement is almost a mirror image of the CBD. It recognizes the sovereignty of a country over its biological and genetic resources and the right of a country to regulate ABS. It provides a broad framework and makes it the responsibility of each country to put in place such measures – legal, administrative or policy – for ABS; to establish procedures for the grant of PIC, disseminate information on the status of access applications; and to establish links with the regional clearing house.

The agreement leaves it to countries to formulate rules and procedures to implement MAT and benefit-sharing. PIC is made mandatory and the agreement specifies the minimum information that must accompany an application.

Some provisions have a regional dimension. The value of the agreement lies in this facet. A clear objective of the agreement is to set minimum standards for ABS. This is to ensure

⁵³ For further information on the Ethiopian contract, see: Gurdial Singh Nijar, *Traditional Knowledge and Intellectual Property Interface: Responses, Policies and Options for Developing Countries*, Centre of Excellence for Biodiversity Law, 2006, (forthcoming publication).

⁵⁴ *Contra*: Philippe Cullet, *Intellectual Property Protection and Sustainable Development*, Lexis Nexis-Butterworths, 2005, at 183.

that there is a regional minimum criteria for ABS. This will deter bioprospectors from seeking the 'best' (least desirable – from the providers' point of view) terms for ABS. This coupled with the requirement to inform the clearing house of all access applications may help to reinforce a stronger regional framework. Again, the details of putting in place regional measures and processes are left to be dealt with as part of the work after the agreement comes into force.

We now look at the key features of this Agreement and the obligations that Malaysia will have to adhere to after ratification.

1. The Preambular paragraphs: minimum standards on ABS, against biopiracy, IR

Most international or regional agreements start off with preambles. Although part of the agreement, it is not the operative part of the agreement. Hence it is not binding. It provides the background and the reason for the agreement. Preambles can be referred to, to resolve any doubt in the main terms of the agreement.

In international agreements, they may sometimes reflect the more progressive thoughts which could not be agreed to by consensus. They then may provide a road map as to the future direction of the agreement.

An important preambular paragraph states that ABS are currently inadequately regulated and thus the '*...urgent need to protect the Parties interests especially from biopiracy or illegal, unreported, unauthorized bioprospecting*'.⁵⁵

The preambles also support the development of an international regime on ABS; and declare the need to establish uniform and consistent access regulations in the region by setting minimum requirements for national implementation to maximise opportunities for conservation and sustainable use of biological and genetic resources.

2. Principles

Principles provide the general framework within which concrete obligations are framed. Members must adhere to these tenets when implementing national legislation and policies. The principles require Parties to

- ensure fair and equitable benefit-sharing at the community, national and regional level;

⁵⁵ A preambular paragraph in the initial 2000 Draft text stating as a fundamental principle that the prior informed consent of the member State and its indigenous peoples and local communities embodying traditional lifestyles would have to be secured before access can take place is deleted from the present text.

- recognize, respect and preserve and maintain TK of indigenous and local communities;
- ensure PIC for access;
- facilitate exchange and utilization of food crop germplasm to enhance food security in the region;
- consider the environmental and social impacts of access in conformity with regional guidelines..

The regional facets of the principles (the last 2 bullets) will impact a country's law. There has to be some measures to facilitate germplasm exchange and utilization. And a mechanism to ensure that due cognizance is taken of regional guidelines that give rise to environmental and social impacts of access.

What is less clear is how and what benefits are to be shared at the regional level. This is intended to apply to 'shared' resources that are endemic to the region; or where the genetic resources or associated TK for the commercialization of a product is from multiple member countries. The provision on benefit sharing makes reference to this in terms that is not free from doubt, as we shall presently see.

3. Objectives

Objectives are similar to principles in that they provide the framework within which actions have to be taken. It sets the basis for the specific obligations in the subsequent articles. Implementation must conform to these objectives. The objectives also provide a basis by which to monitor compliance.

One of the objectives is to accord recognition and protection to traditional knowledge of indigenous peoples and local communities, and to facilitate the fair and equitable sharing of benefits with the communities where traditional knowledge is utilized. Another is to establish effective and participatory measures for the grant of prior informed consent, 'taking into account national perspectives and priorities'. And setting minimum standards for ABS. The regional dimension is seen in the provisions that require cooperation to facilitate access and to encourage sharing of resources, technologies, experiences and information; and in encouraging R&D, adopting new technologies, promoting technology transfer and capacity building at the regional level. There is also the objective of cooperating to strengthen the voice of the parties in international agreements and negotiations.

4. Scope

The agreement covers all biological and genetic resources of the Parties, including the associated TK, with the exclusion of genetic resources of human origin. Access to biological and genetic resources does not mean access to the TK associated with the resource. Access to such TK must be expressly indicated in the application for access.

Derivatives are included in the scope as well, as the agreement requires the information accompanying the PIC application to disclose benefits from derivatives and products arising from the commercial and other utilization of the biological and genetic resources. 'Derivatives' is defined.

Indigenous and local communities are not to be prevented from the traditional uses of biological and genetic resources in accordance with their customary practices and traditions. They do not have to apply for access. All other individuals, agencies and institutions must comply with access regulations established by the Parties.

5. Access Instrument

The nature of the access instrument will be determined by each Party's national policy and legislation. It must incorporate the minimum terms and conditions prescribed by the agreement.

6. Implementation

The agreement will be implemented by the Conference of the Parties.

7. Regional Clearing House Mechanism

A Regional Clearing House Mechanism will be established. Its responsibilities include:

- Providing relevant information to resource users and the competent national authorities. The information will be subject to 'appropriate confidentiality' provisions;
- Providing technical and legal support to competent national authorities;
- Establishing a database of biological and genetic resources and their associated traditional knowledge of the Parties, subject to national arrangements;

8. Designating competent national authorities

The member States must designate their competent national authorities to fulfill the obligations under the agreement.

9. Settlement of Disputes

Any dispute between the Parties as to the interpretation or application of, or compliance with, the agreement will be settled amicably by consultation or negotiation.

10. Prior Informed Consent and Participation of Key Stakeholders; Customary Law

The prior informed consent of the Party providing the biological and genetic resources is necessary for access. The national competent authority must establish procedures for securing the consent. The original 2000 draft required the competent national authority of a State to establish legally-binding procedures for the determination of prior informed consent up to the local level; and there were elaborate procedures prescribed leading to the grant of prior informed consent at the local level. Also required was the 'active involvement' of indigenous peoples and local communities embodying traditional lifestyles. It also stipulated that the prior informed consent process must respect and comply with the customary laws, practices and protocols of indigenous peoples and local communities. And that the disclosure of any information relating to the access must be in a language understandable to the local communities. These provisions have been deleted.

However, the essence of these earlier provisions is maintained. Now it is up to a Party to establish procedures for the granting of prior informed consent at the national and local levels with the direct involvement of resource providers.

The Parties must provide in their access regulations that any application for prior informed consent must be accompanied by a full disclosure of the following information:

- legal entity and affiliation of the applicant and/or collector and contact person when the entity is an institution;
- type and quantity of the resource to which access is sought;
- the period when the collection activities will take place;
- the geographical prospecting area;
- evaluation of how the access activity may impact on conservation and sustainable use of biodiversity;
- information regarding intended use (example: taxonomy, collection, research, commercialization and expected results;
- description of research and development methodology; and
- the types/kinds of benefits and indication of benefit-sharing arrangements that could come from obtaining access to biological and genetic resources, including benefits from derivatives and

products arising from the commercial and other utilization of such resources.

A provision in the 2000 draft that any denial of access by a Party will be notified to others through the regional clearing house mechanism for their information and appropriate action is deleted from the present text. There is nonetheless an obligation to disseminate information on denials of access applications; as well as to provide information to the regional clearing house. A reading of these provisions suggests that information on denials of access will be provided to the clearing house. Additionally, once such information, as well as that of the regulations, have been provided to the clearing house, other Parties will be obliged to make sure those provisions and decisions are not undermined. It follows that each Party's law and policy should reflect the reciprocal recognition and enforcement of the decisions of other Parties.

11. Fair and Equitable Sharing of Benefits

Each party is to establish processes to ensure the fair and equitable sharing of benefits arising from the use of TK and resources. The earlier draft stated that any benefit sharing arrangements must not 'negatively interfere' with traditional knowledge systems and practices of indigenous peoples and local communities. This is deleted from the present text. As is also deleted a provision that stated that member States must recognize the indigenous peoples and local communities as legitimate users and custodians of biological and genetic resources, and creators of TK. The present law in any event implies these provisions. All resource providers,⁵⁶ must be 'actively' included in the negotiation of benefits on the basis of a full disclosure of potential benefits and risks arising from the use of the resource. such a provider is defined as persons or entities supplying biological and genetic resources, including governments, local authorities, land owners and bodies governing ex-situ collections.

The negotiation of the kind of benefit sharing arrangements that may come in the form of technology transfer, capacity building, monetary and non-monetary benefits, is for the State to decide. The earlier text listed a minimum set of requirements which must include the following:

- The participation of nationals in research activities;
- The sharing of research results, including all discoveries;
- A complete set of all voucher specimens left in national institutions;
- Access by nationals to all national specimens deposited in international *ex situ*-collections;
- The receipt by resource providers, without payment of a royalty, of all technologies developed from research on provided materials;

⁵⁶ The earlier 2000 text specified in particular indigenous peoples and local communities embodying traditional lifestyles. This is omitted from the present text, although they are included in the generic term 'resource providers'.

- Fees, royalties and financial benefits; and
- The donation to national institutions of equipment used as part of research.

The omission of the minimum requirements means that Parties are free to enter into any requirements it considers necessary.

If biological or genetic resources are indigenous to two or more Parties, then these parties may collectively discuss with the bioprospector the terms and conditions of access and benefit-sharing. The Parties may discuss the sharing among themselves of these benefits. This provision is unclear. It gives rise to the following questions:

- Who is to decide that the resources exist in two or more parties' territories?
- On whom lies the obligation to initiate the collective discussion?

As an example, if a company seeks a specific resource from Malaysia, must Malaysia do a survey of which other countries of ASEAN the resource exists in? Who is to inform of the collective discussion? Given that biological resources are endemic to the region, this may involve a discussion of all the countries in the group.

- Is the country where the resource exists entitled to share merely because the resource grows in its territory?
- What if the access is to the knowledge in the resource and this knowledge is not shared? country
- What will happen to any agreement entered into without taking into account these provisions?
- How are the benefits to be apportioned?

12. Common Fund for Biodiversity Conservation

A Common Fund has been created for biodiversity conservation. Eliminated are the elaborate provisions in the earlier draft which included money to be sourced from a share in the revenues derived from any commercialization of the use of common and shared resources among the member States; and from charges and fees from each access application; as well as from the benefit-sharing arrangements negotiated by each Party. The present text provides for voluntary contributions, and contributions from other sources, including regional financial institutions and the international donor community. The purpose and application of the Fund is not specified and will need to be spelt out in follow-up rules or guidelines.

13. Environmental and Social Impact and Biosafety Concerns

The 2000 text required conformity with any national, regional and international guidelines on biosafety. Prospects were also held out for a biosafety framework or

protocol to be developed by ASEAN'S Working Group on Nature Conservation and Biodiversity or other relevant ASEAN bodies. This has been deleted. However, there is a requirement to take into consideration the various environmental and social impacts of access to genetic resources in conformity with national, regional and international guidelines. Also there must be a full disclosure of potential benefits and risks arising from the use of biological and genetic resources. This seems to include biosafety risks and concerns.

14. A summary

Each Party must enact a national ABS law with the following provisions:

- a. Scope: biological and genetic resources, derivatives and associated TK: Article 4(1), read with article 6(2)(h) and Article 2, definition of 'derivatives';
- b. Exemptions from Scope: genetic resources of human origin: Article 4(1);
- c. Exemptions from access application provisions: traditional uses of biological and genetic resources and derivatives by indigenous and local communities in accordance with their customary practices and traditions: Article 4(3);
- d. Procedures for PIC: this shall include the direct involvement of resource providers: Article 5(a);
- e. Disclosure in PIC applications of the information set out in paragraph 10 above: Article 6(2);
- f. MAT for benefit sharing arrangements: Article 7(1);
- g. Inclusion of all resource providers in negotiations for MAT: Article 7(1);
- h. Full disclosure of potential benefits and risks arising from the use of genetic resources: Article 7(1);
- i. Processes to ensure fair and equitable sharing of benefits from the use of TK and resources: Article 7(2);
- j. The nature of the benefits: Article 7(3);
- k. Designation of competent authorities and focal points and related rules: Article 10.

It is noted that many of these requirements are similar to those that a country will adopt in implementing the goals and provisions of the CBD.

The Parties must at the regional level provide for the following:

- a. The minimum standards of a national ABS law: preamble.
- b. Mechanisms and provisions for benefit sharing at a regional level: Art 2(d).
- c. Measures for the facilitation of exchange and utilization of food crop germplasm: Article 2(f).
- d. Identification of the national, regional and international guidelines on environmental and social impacts of access to biological and genetic resources: Article 2 (h).
- e. Cooperative measures for facilitating access to these resources: Article 3(d).
- f. Cooperative measures for the sharing of resources, technologies, experiences and information: Article 3(d).
- g. Cooperative measures for R&D, adoption of new technologies, technology transfer and capacity building: Article 3(f).
- h. Measures for stimulating sustainable use and development of biodiversity endemic to the region: Article 3(h).
- i. Set up a forum for intra-regional cooperation for international negotiations: Article 3(i).
- j. Cooperative efforts for a joint approach to protect against biopiracy, including at the WTO/TRIPS, WIPO, and the CBD: preamble, Article 3(i).
- k. Mechanism for the dissemination of information on access regulations: Article 5(c).
- l. Mechanism for the dissemination of information on status of access applications: Article 5(c).
- m. The process for dealing with applications and ABS where resources to be accessed are indigenous to two or more Parties: Article 7(8).
- n. Operational mechanism and rules for the Regional Clearing House: Article 11.
- o. Rules for the purposes for, and manner of, application of the Common Fund for Biodiversity Conservation: Article 12.
- p. Dispute settlement rules of procedures: Article 13.

VI. FREE TRADE AGREEMENTS

Many developing countries have signed, or like Malaysia, are negotiating, bilateral free trade agreements (FTA). On the promise of growth of trade and economic development, deals are being extracted. Some impose stringent commitments with regard to investments and IPRs which may undermine the international gains obtained in the CBD. Some lessons for vigilance can be learnt from the experiences of FTAs concluded by other developing countries.

(a) Peru-US FTA

Peru, for example, recently entered into an FTA with the US. According to a recent study by GRADE, a Lima-based public policy research institute, poor indigenous farmers will be affected by the IPR commitments that now legalize the patenting of genetic resources and traditional knowledge.⁵⁷ The FTA disregards Peru's commitment to Andean law which, as we noted earlier, outlaws the patenting of plants. The Peru-US FTA accepts the US demand to "make all reasonable efforts" to start patenting plants and to never go back on this policy once in place.

Nor does the US-Peru FTA obligate the US patent office to require applicants seeking plant patents to include "disclosure requirements." This is again contrary to the Andean regional agreement which requires applicants to declare where they got their materials or knowledge from, prove that they received permission to use them, and make arrangements to share benefits with their original owners.

(b) Economic Partnership Agreement between Eastern and Southern Africa and the European Community⁵⁸

Another example is the Economic Partnership Agreement (EPA) being negotiated between the European Union and six regional blocs of African, Caribbean and Pacific Island states pursuant to the Cotonou Agreement of 2000. Negotiations on these EPAs are supposed to conclude before 31 December 2007, for entry into force on 1 January 2008.

The EPAs are free trade agreements (FTAs) aiming to liberalise the economies of former European colonies through a package of direct commitments to, and assistance from, the EU.

⁵⁷ Inti Montenegro de Wit, 'FTA Means Deeper Poverty In Peru', 2006, www.twinside.org.

⁵⁸ Title VI - Intellectual property rights, ref: 4th Draft EPA/8th RNF/24-8-2006/, 24 August 2006
Full text of the draft EPA at http://www.bilaterals.org/article.php3?id_article=6014

A recent draft of the EPA with the 16 Eastern and Southern Africa countries deals with rights to local biodiversity and traditional knowledge. The chapter on intellectual property rights endorses the patenting of genetic material, including human genes, and indigenous knowledge from Africa by European companies through a consent-and-compensation procedure. This is meant to "protect" Africa from "biopiracy". If agreed to, patenting life would be acceptable. African countries have fought long and hard against this principle and, as we noted earlier, the African Union model law prohibits patents on life.

The EPA draft also frames rights to African biodiversity and traditional knowledge as "intellectual property".⁵⁹ The proposal extends this interpretation, for the governments that sign it, to the concept of Farmers' Rights under the FAO International Treaty on Plant Genetic Resources for Food and Agriculture.

This effectively undermines TK and the national law and policy options already adopted or agreed to by these countries. The process for these far reaching potential changes has been questioned. An international non-governmental organisation, GRAIN, states, rhetorically, widely held concerns :

Farmers' rights a trade issue? Traditional knowledge to be bought and sold as IPR? Patents on life ok, as long as you pay? And all of this hammered out behind closed doors, far away from the rural communities who are the stewards of Africa's biodiversity and stand nothing to gain from it being sold off to European corporations as intellectual property!

This suggests the urgent need to repudiate the strictures of the requirements of these FTAs as incompatible with the interests of developing countries – especially as they require a roll back of the laws and policies of these countries; and impose restrictions that are more onerous than the multilateral WTO agreement on these issues. They deny the flexibilities that TRIPS allows for countries to shape laws to suit their stage of development. Such breathing space is conspicuously missing from these North-South FTAs.

⁵⁹ All North-South FTAs dealing with traditional knowledge provide for this: see Briefings by GRAIN, 26 Sept 2006.

VII. A CHECKLIST

A checklist of a national ABS agreement consistent with the CBD and the ASEAN Framework law

Such an agreement should consider including the following:

- Authority: an authority designated by the State to deal with all matters relating to access to biological resources;
- Approval: Access only if there is approval by this authority;
- Scope: the resource(s) to be covered in the scope of the law. Includes both biological and genetic resource (ASEAN). The scope also extends to associated TK (ASEAN). To consider whether scope should:
 - include derivatives;
 - have separate consideration for resources based on ownership: public or private;
 - have separate considerations based on the users of the resource: commercial or non-commercial (researchers in public institutions)?
- The information to be supplied in all applications for access including: an assessment of the impact on environment; on sustainable use; and on TK and indigenous peoples and local communities; [possibly at regional level – see later];
- Access applications for TK distinct from applications for access to biological and genetic resources(ASEAN);
- Disseminating information: on access regulation, applications for access that have been approved and denied – including the reasons and circumstances for the denial (ASEAN);
- PIC at the local and national levels with the direct involvement of the resource providers and associated procedures (ASEAN);
- PIC applications must disclose:
 - legal entity and affiliation of the applicant and/or collector and contact person when the entity is an institution;
 - type and quantity of the resource to which access is sought;
 - the period when the collection activities will take place;
 - the geographical prospecting area;

- evaluation of how the access activity may impact on conservation and sustainable use of biodiversity;
 - information regarding intended use (example: taxonomy, collection, research, commercialization and expected results;
 - description of research and development methodology; and
 - the types/kinds of benefits and indication of benefit-sharing arrangements that could come from obtaining access to biological and genetic resources, including benefits from derivatives and products arising from the commercial and other utilization of such resources.
- MAT: its contents and procedures;
 - A prescription of the benefits and the manner of sharing, including criteria for ascertaining 'fair and equitable';
 - Whether to prescribe processing fee and other upfront payments;
 - Restrictions for considering access based on the objectives of the CBD;
 - Exemptions from access application by indigenous and local communities for traditional uses of biological and genetic resources in accordance with their customary practices and traditions (ASEAN).
 - Other general restrictions including those on future use such as limits on the amount and manner of collecting, on third party use and transfer and specifications for environmentally sound uses;
 - Whether user to provide periodic reports on subsequent use of the resource; also procedure associated with the report – form, frequency and receiving authority;
 - IPRs: who to own, what resource (genetic and associated knowledge, innovation), requirement in applications for IPR for disclosure of compliance with national law (that PIC, MAT and benefit-sharing provisions complied with);
 - Research collaboration and sharing of results;
 - Export restrictions;
 - Biosafety restrictions to ensure the safe exchange of genetic resources;
 - An appeal process where access denied or applicant unhappy with the conditions imposed;
 - Access given for free or at a minimal cost to the crops listed in Annex 1 of the ITPGRFA if these are declared to be in the public domain and under the management and control of the Parties.⁶⁰ Access should be for free or at a minimal cost. There can be no IPR or other rights claimed that could limit the facilitated access to the genetic resource or their genetic parts or components 'in the form received by the multilateral system;
 - Benefit sharing of crops in the preceding bullet on the basis of the standard MTA under the ITPGRFA.

⁶⁰ This includes Annex 1 materials held in the *ex situ* collections of the Future Harvest Centres. The treaty states that the Centres' non-Annex 1 materials will be made under substantially the same conditions.

- Regional – amongst Parties to the ASEAN Agreement: cooperation, R&D, sharing of benefits where resources in product from regional source; transfer of technology, development of new technologies, sharing of resources (including the exchange of germplasm), technologies, experiences and information, consider environmental and social impacts of access to Parties; and ensuring that the legislative, administrative and policy measures of each Party in implementing the agreement are not undermined; providing information to the regional clearing house.
- Regional: provision for collective determination of the terms and conditions of access and benefit-sharing with the applicant, where biological or genetic resources are indigenous to two or more Parties. This includes determining how the benefits are to be apportioned (ASEAN).
- Regional: provision to authorize the voluntary contribution to the ASEAN Common Fund for Biodiversity Conservation.

Note: The regional obligations could be the subject of a separate instrument designed to deal specifically with the regional facets of the ASEAN Framework agreement.

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